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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/620,495	07/16/2003	Robert F. Rioux	10123/00501	9066

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Patrick J. Fay, Esq.
FAY KAPLUN & MARCIN, LLP
Suite 702
150 Broadway
New York, NY 10038

EXAMINER	
AHMED, AAMER S	

ART UNIT	PAPER NUMBER
3763	

DATE MAILED: 11/18/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/620,495	RIOUX ET AL.	
	Examiner	Art Unit	
	Aamer S. Ahmed	3763	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *16 July 2003*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-30* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-23* is/are rejected.

7)☒ Claim(s) *11* is/are objected to.

8)☒ Claim(s) *24-30* are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *7/16/03, 1/27/05*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims 1-23, drawn to a device for preventing closure of a surgically created resection cavity, classified in class 604, subclass 19.

II. Claims 24-30, drawn to a method of treating tissue surrounding a surgically created resection cavity, classified in class 600, subclass 29.

The inventions are distinct, each from the other because of the following reasons:

Inventions device for preventing closure of a surgically created resection cavity and a method of treating tissue surrounding a surgically created resection cavity are related as process and apparatus for its practice. The inventions are distinct if it can be shown that either: (1) the process as claimed can be practiced by another materially different apparatus or by hand, or (2) the apparatus as claimed can be used to practice another and materially different process. (MPEP § 806.05(e)). In this case the apparatus can also be used to deliver drugs.

During a telephone conversation with Oleg Kaplun on June 7, 2005 a provisional election was made without traverse to prosecute the invention of a device for preventing closure of a surgically created resection cavity, claims 1-23. Affirmation of this election must be made by applicant in replying to this Office action. Claims 24-30 are withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to a non-elected invention.

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one

or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Claim Objections

Claim 11 is objected to because of the following informalities: Claim 11 refers back to itself. It is assumed that claim 11 is intended to depend from claim 1. Appropriate correction is required.

Information Disclosure Statement

Each IDS must include a list of all patents, publications, applications, or other information submitted for consideration by the Office (see 37 CFR 1.98(a)(1) and (b)), and MPEP § 609 subsection III. A(1) states, "the list ... must be submitted on a separate paper." Therefore, the references cited in the Search Report: General Surgical Innovations, http://www.americanwebsite.com.comps1/gsi/pages/corporate/profile.htm has not been considered. Applicant is advised that the date of submission of any item of information or any missing element(s) will be the date of submission for purposes of determining compliance with the requirements based on the time of filing the IDS, including all "statement" requirements of 37 CFR 1.97(e). See MPEP § 609 subsection III. C(1).

Specification

The disclosure is objected to because of the following informalities: element 18 in Figure 1 is not disclosed in the specification.

Appropriate correction is required.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-3, 6-7, 9-17 and19-22 are rejected under 35 U.S.C. 102(b) as being anticipated by Racchini et al ('568). Racchini discloses a device comprising an insertion member 11 having a distal end and a proximal end and an inflatable balloon 12 deployable from the distal end of the insertion member, an inner chamber 13 of the balloon, which is fluidly coupled to the lumen to receive an inflation fluid. Moreover, Racchini discloses that the balloon 12 is insertable through the insertion member in a deflated configuration (column 3) and that the spherical balloon 12 further comprises a polymeric coated retention layer formed on the outer surface 22. Furthermore, Racchini teaches that the balloon member further comprises a plurality of perforation on the outer surface (column 7) and an inner inflation fluid chamber and an outer therapeutic agent chamber, which are sealed from one another (column 7). Moreover Racchini teaches that the polymeric coating on the radiation therapy balloon is adapted to time release a chemotherapeutic agent (See column 16).

Therefore Racchini reasonably appears to teach and disclose every element of claims 1-3, 6-7, 9-17 and 19-22.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 4 and 5 are rejected under 35 U.S.C. 103(a) as being unpatentable over Racchini et al ('568) in view of Segal ('752). Racchini discloses an expandable insertion member as described above in reference to claim 1. Racchini fails to disclose a luer at the proximal end, adapted to introduce inflation fluid to the inflatable portion via the lumen nor does Racchini disclose a port at the proximal end.

Segal ('752) describes a similar expandable insertion device wherein a luer 66 and port 71 are present at the proximal end of the member.

It would have been obvious to one of ordinary skill in the art at the time of the invention by the applicant to modify the expandable insertion member device of

Racchini by adding a luer and port at the proximal end in order to introduce inflation fluid and the radioactive seed into the insertion member as taught by Segal.

Claim 23 is rejected under 35 U.S.C. 103(a) as being unpatentable over Racchini et al ('568) in view of Winkler et al ('142). Racchini discloses an expandable insertion member as described above in reference to claim 1. Racchini fails to disclose that the expandable portion is sized to fill a lumpectomy resection cavity.

Winkler et al ('142) describes a similar expandable insertion device wherein the expandable portion is sized to fill a lumpectomy resection cavity. (See column 8).

It would have been obvious to one of ordinary skill in the art at the time of the invention by the applicant to modify the expandable insertion member device of Racchini such that the expandable portion is sized to fill a lumpectomy resection cavity in order to deliver a chemo-therapeutic agent to the site as taught by Winkler.

Claims 8 and 18 are rejected under 35 U.S.C. 103(a) as being unpatentable over Racchini et al ('568) in view of Winkler ('194). Racchini discloses an expandable insertion member as described above in reference to claims 6 and 17. Racchini fails to disclose that the therapeutic agent is paclitaxel.

Winkler ('194) describes a similar expandable insertion device wherein the therapeutic agent is paclitaxel. (See column 6).

It would have been obvious to one of ordinary skill in the art at the time of the invention by the applicant to modify the expandable insertion member device of Racchini by adding the therapeutic agent paclitaxel as taught by Winkler ('194) in order to describe a common chemotherapeutic agent.

Conclusion

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

U.S. Pat. No. 5,910,101	Andrews et al.
U.S. Pat. No. 6,645,135	Bhat
U.S. Pub. No. 2002/0165520 A1	Forman
U.S. Pat. No. 5,954,706	Sahatjian
U.S. Pat. No. 5,628,730	Shapland et al.
U.S. Pat. No. 5,899,882	Waksman et al.
U.S. Pat. No. 6,083,148	Williams

NICHOLAS D. LUCCHESI
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 3700